New Pulse Oximetry Sensors with Low Saturation Accuracy Claims – A Clinical Evaluation.

Cox PN. *Anesthesiology.* 2007; 107: A1540.

Introduction

Both Masimo and Nellcor claim to have pulse oximetry systems and sensors that are accurate for oxyhemoglobin saturations below 70%, and therefore appropriate for use on congenital cyanotic cardiac disease patients. This claim has previously been unmet by any commercial pulse oximetry technology. This study compares the accuracy of the Masimo Radical with LNOP Blue sensor and the Nellcor N-600 with Max-I LoSat sensor on congenital cyanotic cardiac lesion patients in the ICU.

Methods

Twelve pediatric ICU patients with congenital cyanotic cardiac lesions were monitored with an LNOP digit sensor, an LNOP Blue sensor, each attached to a Masimo Radical, and a Nellcor Max-I sensor with LoSat attached to an N-600. A total of 60 arterial blood gases were obtained as clinically needed and compared to the pulse oximetry readings from the three sensors. A paired t-test was used to compare the A_{RMS} values from each of the three sensors to the blood gas readings. Laboratory CO-Oximetry readings ranged from 85 to 56.1% with a mean of 72.3%.

Results

	Masimo SET Radical with Blue Sensor	Nellcor N-600 and Max-I sensor with LoSat	LNOP Sensor
Mean ± SD	70.5 (7.5)	75.9 (5.6)	75.2 (6.4)
Range %	87 - 52	89 - 61	91 - 57
Bias	-1.91	3.81	1.86
Precision	3.50	5.26	6.24
ARMS	**3.97***	**6.49**	**6.51**
R^2 value	.886	.698	.60

Table 1- The bias, precision, A_{RMS} and regression analysis for the new sensors with low saturation accuracy claims, and the LNOP sensor in 12 children with congenital cyanotic cardiac lesions. Paired t-test of the A_{RMS} shows a significant difference between the Masimo LNOP Blue and the other sensors, $p < 0.001$.

Conclusion and Author's Comment:

Although the N-600 and Max-I sensor with LoSat claims accuracy of 3.0 A_{RMS} in patients with saturations from 60 – 80%, that accuracy claim was not met and the accuracy was not significantly different from the Masimo LNOP sensor on these patients. The Masimo Radical with Blue sensor, on the other hand, claims accuracy of 4.0 A_{RMS} on saturation levels between 60-80% and had an accuracy of 3.97. The author concludes, "Despite advances in technology, only the Masimo Blue sensor demonstrates acceptable accuracy as demonstrated by a smaller bias and precision and A_{RMS}."